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## NOTICE OF ALLOWANCE AND FEE(S) DUE

23552 7590 10/06/2009

MERCHANT & GOULD PC  
P.O. BOX 2903  
MINNEAPOLIS, MN 55402-0903

EXAMINER

CHERRY, STEPHEN J

ART UNIT

PAPER NUMBER

2863

DATE MAILED: 10/06/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,682

07/21/2006

Peter Gill

07500.0455USWO

2112

TITLE OF INVENTION: ANALYSIS OF DNA

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	01/06/2010

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

### HOW TO REPLY TO THIS NOTICE:

#### I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

# **PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE  
Commissioner for Patents  
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

23552 7590 10/06/2009

**MERCHANT & GOULD PC**  
P.O. BOX 2903  
MINNEAPOLIS, MN 55402-0903

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

## **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,682	07/21/2006	Peter Gill	07500.0455USWO	2112

TITLE OF INVENTION: ANALYSIS OF DNA

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	01/06/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHERRY, STEPHEN J	2863	702-019000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 \_\_\_\_\_
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 \_\_\_\_\_
- 3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_

Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Registration No. \_\_\_\_\_

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/564,682	07/21/2006	Peter Gill	07500.0455USWO	2112
23552	7590	10/06/2009	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			CHERRY, STEPHEN J	
			ART UNIT	PAPER NUMBER
			2863	
DATE MAILED: 10/06/2009				

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 628 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 628 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

**Notice of Allowability**

Application No.

10/564,682

Applicant(s)

GILL ET AL.

Examiner

Art Unit

Stephen J. Cherry

2863

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8-10-2009.
2. ☒ The allowed claim(s) is/are \_\_\_\_\_.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |                                                                                                                               |                                                                                        |
|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                   | 5. <input type="checkbox"/> Notice of Informal Patent Application                      |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                          | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date <u>7-21-2006</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                    | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|                                                                                                                               | 9. <input type="checkbox"/> Other _____.                                               |

***Election/Restrictions***

Claims 34-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8-10-2009.

In the reply dated 8-10-2009, applicant clearly elected group I, described in the Requirement for Restriction dated 6-10-2009 as claims 1-33. Further, applicant, in the reply dated 8-10-2009, chose to cancel claims 1-23 of the elected group, and added new claims 37 and 38 to the elected group. As such, the remaining elected claims 24-29 and 37-38 have been examined. Further, non-elected claims 34-36 have been canceled with applicant's authorization in the examiners amendment, below.

**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. DeMaster on 9-17-2009.

The application has been amended as follows:

Please replace the claims with the following:

24. A method of providing information on the likelihood of a result arising due to contamination in a method of analysis:

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the method of analysis including a threshold which determines the analysis protocol to be applied to the analysis of DNA in a test sample;

the method of providing information including:

in respect of one or more negative controls, obtaining information on whether or not DNA is suggested as present in the one or more negative controls;

determining the probability of DNA being suggested as present in the one or more negative controls, the determination being based on the number of the one or more negative controls which suggest DNA is present compared with the total number of the one or more negative controls considered;

the probability of DNA being suggested as present in the one or more negative ~~controls~~ ~~control~~ being equated to the probability of the test sample ~~DNA samples~~ being contaminated;

the method of providing information further including:

in respect of one or more DNA samples, obtaining information on whether or not DNA is suggested as present in the one or more DNA ~~samples~~ ~~sample~~;

obtaining information about the quantity of DNA in the one or more DNA samples;

in respect of one or more second negative ~~controls~~ ~~control samples~~, which may be the same or different to the one or more negative controls, obtaining information on whether or not DNA is suggested as present in the one ore more second negative ~~controls~~ ~~control~~;

obtaining information about the quantity of DNA in the one or more second negative controls;

simulating one or more mixtures, the mixtures each being formed from a pairing of a second negative control sample and a DNA sample taken from amongst the one or more second negative ~~controls~~ ~~control samples~~ and the one or more DNA samples;

establishing the proportion of mixtures for one or both of the following types of simulated mixture:

DNA suggested as present from second negative control sample only;

DNA suggested as present from both DNA sample and second negative control-sample;

determining a likelihood ratio in respect of a result arising which exceeds or which matches or exceeds the threshold in the method of analysis for one or both of the types of simulated mixture.

25. A method according to claim 24, wherein the method of providing further information provides information on possible errors, and the information on possible errors is an indication as to the number of the one or more second negative controls which contain a quantity of DNA above the threshold and / or the information on possible errors is an indication as to the number of ~~contaminated~~ samples which contain DNA above the threshold.

26. A method according to claim 24, wherein test samples above or at and above the threshold are subjected to a first analysis protocol and/or test samples at and below or below the threshold are subjected to a second analysis protocol.

27. A method according to claim 24, wherein a probability of achieving a given likelihood ratio is determined and such a determination is made in respect of one or more likelihood ratio levels and/or is made in respect of one or more values for the threshold values.

28. A method according to claim 24, wherein the method includes varying the threshold to give a predetermined likelihood ratio and/or predetermined probability of achieving a likelihood ratio.

29. A method according to claim 24 in which the method is applied independently to different operating organisations and/or different processing lines within organisations.

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34. Cancelled

35. Cancelled

36. Cancelled

37. A method according to claim 24 in which the method includes adjusting the level of the threshold to alter the number or proportion of the one or more second negative controls on one or other side of the threshold.

38. A method according to claim 24 in which the method includes adjusting the level of the threshold to reduce the number or proportion of the one or more second negative controls above the threshold.

Claims 24-29 and 37-38 are allowed.

The following is an examiner's statement of reasons for allowance:

Claim 24 recites, "simulating one or more mixtures, the mixtures each being formed from a pairing of a second negative control and a DNA sample taken from amongst the one or more second negative controls and the one or more DNA samples; establishing the proportion of mixtures for one or both of the following types of simulated mixture: DNA suggested as present from second negative control only; DNA suggested as present from both DNA sample and second negative control; determining a likelihood ratio in respect of a result arising which exceeds or which matches or exceeds the threshold in the method of analysis for one or both of the types of simulated mixture".

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This feature, combined with additional claimed subject matter, overcomes the prior art of record.

Regarding 35 U.S.C. 101, claim 24 recites a simulation of mixtures, disclosed in the specification as performed by MATLAB. MATLAB is a commercially available computer simulation application; therefor, carrying out the invention requires the use of a computer which involves a tie to another statutory class.

US 2006/0281134 to Love discloses similar subject matter, but does not disclose claimed features.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen J. Cherry whose telephone number is (571) 272-2272. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Drew A. Dunn can be reached on (571) 272-2312. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. C./  
Examiner, Art Unit 2863

**Drew A. Dunn**  
**/Drew A. Dunn/**  
**Supervisory Patent Examiner, Art Unit 2863**